Criteria for prescribing dabigatrin extexilate and rivaroxaban really appropriate?

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Criteria for Prescribing Dabigatrin Extexilate and Rivaroxaban Really Appropriate? Authors' Reply

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We are grateful to Basaran et al[1] for their relevant comments.

We agree that "much effort is needed for selection of inappropriateness criteria." In our study, appropriateness criteria were defined after a review of the literature in the field, including original research articles, systematic reviews/meta-analyses, and clinical guidelines. However, data or recommendations were either divergent or lacking for some important criteria (eg, first choice of oral anticoagulant, clinical relevance of some drug interactions, switch of direct oral anticoagulants [DOACs] in case of renal insufficiency). In addition, discrepancies in the definition of nonvalvular atrial fibrillation (NVAF) were observed between large phase III trials. In light of these limitations, we defined *appropriateness* according to available evidence and expert opinion.

Because of the lack of consensus in the definition of NVAF, we decided to use the broadest definition used in the RE-LY study.[2] We considered the indication as inappropriate in the following situations: patients with severe aortic or mitral insufficiency, severe aortic or mitral stenosis, or with a prosthetic valve. In line with the recent American and European guidelines, aortic stenosis could have been excluded from this list. In our study, only 2 out of the 8 patients had an inappropriate indication resulting from severe aortic stenosis. If we consider them as appropriate, the prevalence of inappropriate indication would change from 12% to 9%. Therefore, the impact of this sensitivity analysis on the overall conclusion remains limited.

In response to the second comment, based on current recommendations of the European Society of Cardiology, we considered as an appropriate indication a patient with NVAF and a CHA_2DS_2VASc score ≥1, except for the situation of female patients with gender alone as a single risk factor (because they do not need anticoagulation if they clearly fulfill the criteria of age <65 years and lone AF).[3] In our study, no patient had a CHA_2DS_2VASc score of 0, 3 patients had a score of 1 (one being a woman <65 years and with lone AF), and all other patients (n = 66) had a score ≥1.

Regarding the last comment, we agree that there is no international consensus on switching from one DOAC to another because of renal insufficiency, but recommendations were proposed by scientific associations.[4] In our study, only 1 out of the 3 inappropriate ratings for the "choice" criterion was related to renal function. This patient had moderate renal impairment, failed to be well controlled with a vitamin K antagonist, and was receiving dabigatran etexilate (DE) at the time of the study. We considered rivaroxaban to be more appropriate because rivaroxaban is less affected by impaired renal function than DE.[4] The 2 other patients with an inappropriate rating had swallowing problems and were receiving DE. We considered DE as inappropriate because crushing of the tablet is only allowed for rivaroxaban.

In conclusion, in the absence of international consensus, choices were made to identify the best criteria for appropriate use of DOACs. Sensitivity analysis using modified criteria support the conclusion that inappropriate use of DE and rivaroxaban in patients with NVAF is frequent.

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